RELIANCE™ PI PROCESS INDICATORSTRIPS FOR RELIANCE ENDOSCOPE PROCESSING SYSTEM 510(K) SUMMARY

K043482

Date	July 5, 2006
Submitter	STERIS Corporation 5960 Heisley Road Mentor Ohio 44060 USA Telephone: 440-354-2600
Contact	Nancy A. Robinson Director, Advanced Sterilization STERIS Corporation 5960 Heisley Road Mentor, OH 44060 USA Tel.: 440-392-7742 Fax: 440-392-8955 E-mail: nancy_robinson@steris.com
Device name	Proprietary Name: Reliance™ PI Process Indicator Common Name: Physical/Chemical Process Indicator Classification Name: Physical/Chemical Process Indicator
Legally marketed devices to which substantial equivalence is claimed	The Reliance PI Process Indicator is substantially equivalent to the STERIS PROCESS Chemical Monitor for the STERIS SYSTEM 1 Processing System (K921559) based on the following comparison:

Property	Reliance™ PI Process Indicator	STERIS PROCESS Chemical Monitor (K921559)
Intended use	The Reliance PI Process Indicator is a single use chemical indicator designed to change from the "START" dark pink color to the "ENDPOINT" orange color or lighter upon exposure to an effective dose of **peracetic acid** generated from Reliance DG Dry Germicide during the Reliance Endoscope Processing Cycle.	Intended for use by healthcare providers for the detection of **peracetic acid**, the active ingredient of STERIS 20 Sterilant, during the STERIS SYSTEM 1 sterilization cycle.
Design	0.20" square, off-white reagent pad affixed to one end of a 3.25" x 0.20" polystyrene strip.	0.20" square, off-white reagent pad affixed to one end of a 3.25" x 0.20" polystyrene strip.
Packaging	Fifty indicator strips per screw-capped bottle with desiccant.	Fifty indicator strips per screw-capped bottle with desiccant.
Indicator agent	Triphenylmethane dye	Crystal violet

Legally marketed devices to which substantial equivalence is claimed, continued

Property	Reliance™ PI Process Indicator	STERIS Process Chemical Monitor (K921559)
Color change upon exposure to appropriate concentrations of peracetic acid.	Dark pink starting color to orange endpoint color or lighter.	Dark purple starting color to pale grey or lighter endpoint color
Mechanism of color change	Oxidation of indicator dye by peracetic acid	Oxidation of indicator dye by peracetic acid
Cycle monitored	The Reliance Process high level disinfection phase consists of a 4-minute generation time and a 6-minute exposure to the peracetic acid use dilution at a temperature of 50 - 57°C.	The STERIS Process sterilization cycle consists of a 12-minute exposure to the peracetic acid use dilution at a temperature of 50 - 56°C.
Endpoint specifications	When the indicator is exposed to peracetic acid (PAA) at a dose ≥ 11,500 mg/L PAA min generated from Reliance DG Dry Germicide during the Reliance Endoscope Processing Cycle, there will be a complete change to endpoint color or lighter in 100% of the indicator strips. When the indicator is exposed to the minimum recommended dose of 9000 mg/L PAA min or less, there will be an incomplete color change in 100% of the indicator strips.	When the indicator is exposed to production lots of STERIS 20 Sterilant, there should be a complete color change to endpoint. When the indicator is exposed to a lowered charge of the STERIS 20 Sterilant, there should be an incomplete color change.
Shelf-life	Based on current testing: 2 years unopened 6 months after opening	2.5 years unopened 6 months after opening

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Device description	The **Reliance PI Process Indicator** is a single use chemical indicator strip that is designed to confirm an effective dose of peracetic acid (PAA), the active ingredient generated from Reliance DG Dry Germicide in the **Reliance Endoscope Processor's** HLD cycle. This test strip consists of a 0.2-square inch reagent-containing indicator pad attached to one end of a 0.2 x 3.25-inch polystyrene handle. The indicator pad contains an indicator dye with a background dye that together form a dark pink color. Upon exposure to the effective dose of PAA generated during the Reliance Endoscope Processing Cycle, the indicator dye only is oxidized by the Reliance DG Dry Germicide use dilution during the Reliance Endoscope Processing Cycle. During the processing cycle, the indicator pad color transitions through a lighter pink color until an orange coloration, based on the background dye, is visible.
Intended use	The **Reliance PI Process Indicator** is a single use chemical indicator designed to change from the "START" dark pink color to the "ENDPOINT" orange color or lighter upon exposure to an effective dose of peracetic acid generated from Reliance DG Dry Germicide during the Reliance Endoscope Processing Cycle. The **Reliance PI Process Indicator** is designed to be used exclusively for the independent monitoring of the **Reliance Endoscope Processing System**. The Reliance PI Process Indicator is not an indicator of load disinfection or cleaning efficacy.
Performance Testing	The **Reliance PI Process Indicator** was developed and validated in accordance with FDA's Guidance document: *Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants (2000)* A summary of this testing follows: **Kinetic Studies** validated the Reliance Endoscope Processor's delivery of peracetic acid in concentrations appropriate for PI performance testing. Specially packaged Reliance DG Dry Germicide containers with two targeted PAA generation capacities were used for the majority of Reliance PI Process Indicator performance validation. **Sensitivity Studies** demonstrated that the Reliance PI Process Indicator develops the complete ENDPOINT color (pass) when the dose of PAA is $\geq$ 11,500 mg/L PAA min, and fails to reach that color (incomplete endpoint reading, not acceptable) when the PAA dose is < 9000 mg/L PAA min. **Specificity Testing** confirmed that the two components of the Dry Germicide's container cannot independently cause a color change to ENDPOINT.

Performance Testing, continued	**Repeatability and Precision** of the reaction was demonstrated over numerous repeated assays using varying parameters of use. **Stability of the PI Color** was confirmed when reading delays occur in the closed processor or after the PI is removed from the processor. **Stability of Strips** in unopened bottles was established through 24 months of storage under labeled storage conditions. Use-life of the opened bottle was validated through 6 months after opening. Periods of storage outside labeled conditions did not affect performance. **Performance** of strips was validated in the Reliance Processing Cycle with and without worst case washing phases, with maximum air purge time and when combined with conditions of delayed PI reading. When used during a simulated-use study of the **Reliance Endoscope Processing System** in which eight flexible endoscopes were processed, the Reliance PI Process Indicator detected the intended levels of PAA by demonstrating "complete" PI readings in each of the 27 cycles. When used during a simulated-use study of the **Reliance Endoscope Processing System** in which three worst-case flexible endoscopes were processed with a PAA dose of 9000 mg/L PAA min (minimum recommended dose), the Reliance PI Process Indicator demonstrated an "incomplete" PI reading in each of the 9 cycles. High level disinfection was achieved for each processed device and accessory in each simulated use trial.
Clinical Testing	Although the Reliance Process Indicator was not of itself a subject of a clinical trial, it was employed in an in-use study of the **Reliance Endoscope Processing System**. During this in-use study, the Reliance PI Process Indicator was used in each processing cycle according to the instructions for use. The indicator performed as expected, and was correctly interpreted by the clinical users.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUL 2 1 2006

Re: k043482
Trade/Device Name: Reliance® PI Process Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Physical/Chemical Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: December 16, 2004
Received: December 17, 2004

Dear Mr. Heller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

for Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043482

Device Name: STERIS Reliance™ PI Process Indicator

Indications for Use:

The Reliance PI Process Indicator is a single use chemical indicator designed to change from the "START" dark pink color to the "ENDPOINT" orange color or lighter upon exposure to an effective dose of peracetic acid generated from Reliance™ DG Dry Germicide during the Reliance Endoscope Processing Cycle.

The Reliance PI Process Indicator is intended to be used exclusively for the independent monitoring of the Reliance Endoscope Processing Cycle. The Reliance PI Process Indicator is not an indicator of load disinfection or cleaning efficacy.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost for DBT

(Div Off)
...of Anesthesiology, General Hospital
...Control, Dental Devices

K043482

(Posted November 13, 2003)